INCREASING PNEUMOCOCCAL VACCINATION RATES AMONG PATIENTS 65 YEARS AND OLDER IN A RETAIL CLINIC

by

Minnerva Estocado Carroz

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As members of the DNP Project Committee, we certify that we have read the DNP project prepared by Minnerva Estocado Carroz, titled Increasing Pneumococcal Vaccination Rates Among Patients 65-Years and Older in a Retail Clinic and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.

Rene Allen Love
_____ Date: Dec 10, 2019
Rene Allen Love, PhD, DNP, PMHNP-BC, FNAP, FAANP

Patricia Daly
_____ Date: Dec 10, 2019
Patricia Daly, PhD, FNP-BC, ENP-BC, FAANP

_____ Date: Dec 10, 2019
Janet L. Rothers, PhD, MS, MA

Final approval and acceptance of this DNP project is contingent upon the candidate's submission of the final copies of the DNP project to the Graduate College.

I hereby certify that I have read this DNP project prepared under my direction and recommend that it be accepted as fulfilling the DNP project requirement.

Rene Allen Love
_____ Date: Dec 10, 2019
Rene Allen Love, PhD, DNP, PMHNP-BC, FNAP, FAANP
DNP Project Committee Chair
College of Nursing

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DEDICATION

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ABSTRACT

Background: Despite the significant morbidity and mortality associated with pneumococcal disease, the national vaccination rates for pneumococcal vaccine for patients 65 years and older fall below the Healthy People goal of 2020. In recent years, there is a growing trend in the use of retail health clinics in the country. These retail health clinics can be an avenue to close the gap in the delivery of pneumococcal vaccination. The purpose of this project is to assess the baseline knowledge of retail health providers and their perception of barriers to pneumonia vaccinations. In addition, a program called The Four Pillars on Immunization Toolkit was implemented to increase pneumococcal immunization rates in a retail health clinic.

Purpose: This project explored the baseline knowledge of the providers and the perceived barriers regarding the delivery of pneumococcal vaccination. Furthermore, The Four Pillars on Immunization Toolkit was utilized to increase immunization in a retail health clinic.

Methods: The baseline knowledge and perception of barriers to delivering the pneumonia vaccination was assessed via an online survey. To increase the pneumococcal vaccination, the participants were educated on the Four Pillars on Immunization Toolkit before actual implementation.

Results: The scores on the knowledge section of the survey ranged from 9% to 81%. These results indicated that providers working in the retail health setting could benefit from pneumococcal vaccination education. The results on the perception of barriers showed that providers working the retail clinics face barriers that prevent the recommendation or the giving of pneumococcal vaccination. In addition, the use of the Four Pillars on Immunization toolkit indicated a 10 % increase in pneumococcal vaccination rate when compared to the previous year.

Conclusion: The result indicated that providers working in the retail clinic are generally knowledgeable about pneumonia vaccination; however, there is a gap noted on certain knowledge questions. In addition, providers noted barriers that prevent the recommendation or the giving of the pneumonia vaccination in this setting. The results suggested the use of the Four Pillars on Immunization Toolkit could be used as a tool in a retail clinic to improve delivery of important immunizations.

INTRODUCTION

Despite being proven effective, adult vaccinations are still underutilized. Adults who are not immunized are at risk of illness, hospitalization, and even death from vaccine-preventable diseases (Center for Disease Control and Prevention, 2016). Immunization is an essential part of preventative health services to improve and eradicate diseases. The use of vaccines to help eliminate diseases is one of the biggest successes of modern science. Vaccinations currently prevent 2-3 million deaths worldwide per year, and vaccinations are considered one of the most cost-effective public health interventions (World Health Organization, 2018). In the United States, the Center for Disease Control and Prevention (CDC) estimated that vaccinations prevented more than 21 million hospitalizations and 732 deaths among children born in the last 20 years (CDC, 2014). Despite the proven efficacy of vaccinations, adult vaccination rates in the United States are consistently lower than Healthy People 2020 goals (Equils et al., 2018). Healthy People 2020 program is a nationwide program that provides a 10-year goal to improve the health of the people (Office of Disease Prevention and Health Promotion, 2019). Because of the low utilization rates for adult vaccinations in the United States, there are still individuals who die from vaccine-preventable diseases. These deaths could be prevented if affected people choose to be vaccinated.

Many vaccinations for adults are recommended and available in the United States. The United States Advisory Committee on Immunization Practices (ACIP), established in 1964 by the U.S. Surgeon General, provides immunization recommendations to the CDC (Smith, 2010). Category ‘A’ recommendations are for routine use in the general population, and Category ‘B’ recommendations are for vaccines recommended by a medical provider based on their medical

judgment (Tan, 2015). The ACIP currently recommends immunizing adults against 15 diseases known to commonly cause significant illnesses. Criteria for administration consider age and risk factors. These vaccines are targeted to prevent illnesses such as influenza, diphtheria, tetanus, pertussis, varicella, human papillomavirus, zoster, mumps, measles, rubella, pneumococcal disease, meningococcal disease, hepatitis A, hepatitis B, and haemophilus influenzae. These diseases remain a public health concern among the adult population because of low rates of immunization (Tan, 2015).

Immunization rates among children are at or above 90% as recommended by the ACIP (Mellerson et al., 2018), but this success has not transpired to the adult population. For example, the immunization rate for pneumococcal vaccination among adults was only at 59.9%, which is significantly below the 90% goal set by Healthy People 2020 (Tan, 2015).

Background Knowledge

One of the 15 infectious diseases prevented through vaccination is *streptococcus pneumonia* (*pneumococcus*). This disease is still the leading cause of serious illness. Once infected with this organism, a person is at risk for bacteremia, meningitis, sinusitis, otitis media, and pneumonia. These diseases are the most common and preventable infectious diseases having a high rate of morbidity and fatality rate worldwide (Cilloniz, Amaro, & Torres, 2016). In 2013 alone, there were approximately 3,700 deaths from pneumococcal meningitis and bacteremia (CDC, 2018).

Another disease that can be prevented with pneumonia immunization is pneumococcal pneumonia. This is by far the most common form of pneumococcal disease in adults, which affects approximately 900,000 Americans each year. In addition, about 5% to 7% of people who

contract the disease do not survive. Further, approximately 400,000 individuals are hospitalized annually from pneumococcal pneumonia (CDC, 2018).

In 2014, the ACIP recommended the routine use of 13-valent pneumococcal conjugate vaccine (PCV13) or its brand name, Prevnar-13 and the 23-valent pneumococcal polysaccharide vaccine (PPSV23) also called the Pneumovax-23 among adults 65 years and older (CDC, 2019). On June 2019, the ACIP recommended the removal of routine use of PCV13 among patients 65 years and older who do not have immunocompromising condition and recommended the decision to immunize is based on shared decision making by the patient and the provider (CDC, 2019) .The recommendation to immunize patients 65 years and older with immunocompromising condition however, has not changed (CDC, 2019).

Despite efforts to increase the rate for adult immunization against pneumococcal diseases, it is still far below the Healthy People 2020 goal of having 90% of adults 65 years and older being immunized with pneumonia vaccine. See Table 1 for estimations of adults who received the pneumonia vaccine (Ecklund, 2017). Efforts to increase pneumonia vaccination include educating the providers, who play a key role. Multiple studies have reported a provider's recommendation was the primary reason why a patient decided to get the immunization (Physicians Weekly, 2015).

TABLE 1. *Estimated proportion of U.S. adults ≥ 65 years old who received pneumococcal vaccines 2010-2014, National Health Interview Survey, United States.*

Pneumococcal Vaccination	2010	2011	2012	2013	2014
rate among U.S. adults ≥ 65	59.7	62.3	59.9	59.7	61.3

Un-weighted sample size (2010-2014):34,640 (Williams et al., 2016)

To estimate the number of Medicare beneficiaries who received the pneumococcal vaccination after the ACIP recommended the vaccine, the CDC (2018) analyzed the data

submitted for reimbursement to the Center for Medicaid and Medicare Services. The results in Figure 1 show claims from September 19, 2009 to September 18, 2017. Receipt of pneumonia vaccine claims for both Pneumovax 23 and Prevnar 13 among Medicare beneficiaries aged 65 years and older ranged from 40% to 59.3% from periods ranging from September 2010 to September 2017.

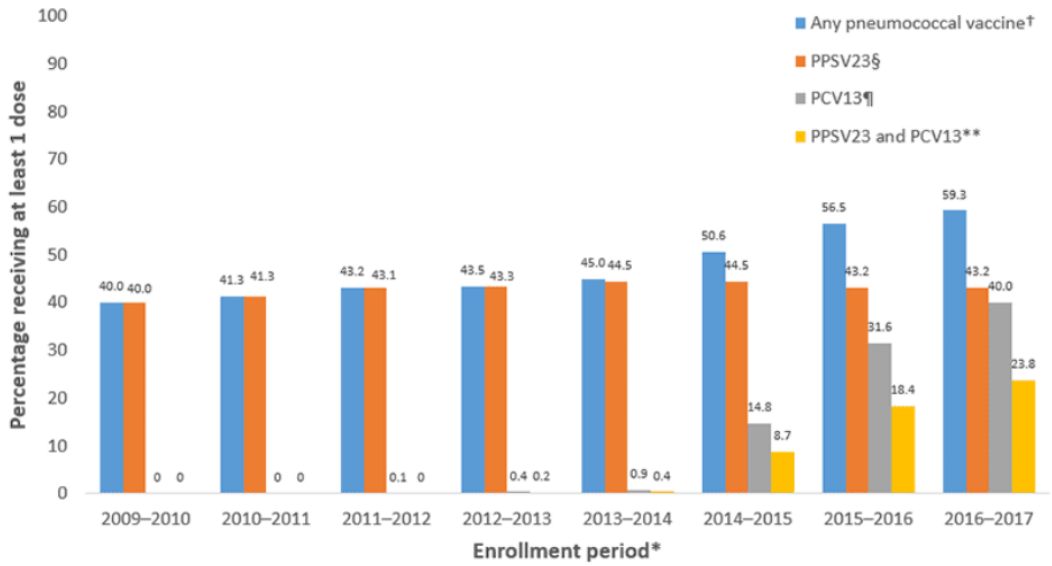


FIGURE 1. Proportion of Medicare beneficiaries aged ≥ 65 years old with claims submitted for pneumococcal vaccination-United States, September 2009-2017 (CDC, 2018).

Economic Burden

Ozawa et al. (2015) reported the economic burden for a vaccine-preventable disease is approximately 9 billion dollars. Of this amount, $5.9 billion was estimated to be related to inpatient treatment and $2.4 billion related to outpatient treatment. To put this number into perspective, the average cost for a hospitalized patient diagnosed with influenza is $5,770. For a patient diagnosed with invasive meningococcal disease, the average cost is $15,600 per hospitalization. The cost to treat pneumococcal diseases in 2015 was a staggering $1.86 billion.

Therefore, a need exists to increase adult pneumococcal vaccination rates to reduce the burden to the economy.

In recent years, a new trend emerged and has become the latest model in the delivery of ambulatory care: retail health clinics (Wang et al., 2010). The number of retail clinics across the country has risen significantly from 130 retail clinics in 2006 to about 1,400 in 2012 (Martsolf et al., 2017). The current estimated number of retail clinics, according to Statistica (2018) is at 2,800 across the United States. Retail clinics are located within 10 minutes from the majority of the urban population. With convenient hours and locations, retail health clinics are becoming accessible to most patients who seek convenient and affordable care (Martsolf et al., 2017). Patients who sought services at retail health clinics report retail health clinics are much more cost effective than emergency room visits. The locations are convenient and wait times are shorter, with proximity to workplaces (Wang et al., 2010). Nurse practitioners and physician assistants who provide episodic care to patients often staff retail clinics. Recent data shows patients are beginning to seek vaccinations and preventative health care at retail health clinic locations (Kaissi, 2015). In the year 2007, 2008 and 2010 there were 39.9%, 36.4%, and 42.0% vaccinations administered during visits to retail-based clinics. The pneumococcal vaccine was administered to 59,849 patients in 2009, which was about 3% of all vaccination visits. In general, the overall vaccination rates show an increase in the number of immunizations given in retail settings (Uscher-Pines, Harris & Burns, 2012). This trend suggests vaccinations in retail clinics can represent an avenue to reach immunization goals for Healthy People 2020.

To date, limited studies exist looking into retail health clinic providers' knowledge and perceived barriers in vaccination delivery. There are also limited studies available on how to increase vaccination delivery in retail health clinics.

Local Problem

The number of cases of pneumonia increases during the flu season. The data from the 2017-2018 influenza season indicates that 21,268 cases of influenza were reported in Arizona. Out of this number, there were 461 deaths related to pneumonia and influenza (Arizona Department of Health Services, 2018). For invasive streptococcus pneumonia alone, Maricopa county had 124 cases in 2017 and 173 cases in 2018 for patients 65 years old and older (Keenan, personal communication, July 2019).

The Kaiser Family Foundation (2017) reported that 75.4% of adults aged 65 and over in Arizona received the pneumonia vaccine, which is a higher percentage than in other states in the USA. However, this rate still falls below the Healthy People 2020 goal. Among Medicare patients residing in Arizona, about 57.6% of Medicare beneficiaries aged ≥ 65 years old had their pneumococcal vaccine, as evidenced by the number of claims submitted to the Center for Medicaid Services (CDC, 2018). The data presented in Table 2 from the CDC (2018) shows a snapshot of Arizona's vaccination rate of Medicare patients in comparison to other states. Comparing Arizona to 10 other representative states, Arizona ranks fourth highest in the number of claims for pneumonia vaccination. Although the number in Arizona is higher, in general this percentage still falls below the Healthy People 2020 goal of a 90% vaccination rate.

TABLE 2. *Proportion of Medicare beneficiaries aged ≥ 65 years old with claims submitted for pneumococcal vaccination, by state, United States, September 2017. A sample of 10 states.*

State	Total enrolled beneficiaries	≥1 dose PPSV23†	≥1 dose PCV13§	Both PPSV23 and PCV13¶	Any pneumococcal**
Alabama	396,887	41.0	30.3	17.9	53.5
Alaska	62,350	26.2	31.5	14.2	43.6
Arizona	521,340	41.0	37.8	21.2	57.6
Arkansas	319,131	42.7	35.8	21.9	56.6
California	2,153,280	40.2	34.5	19.7	55.0
Colorado	345,359	44.0	45.8	26.9	62.9
Connecticut	318,600	45.8	44.4	26.4	63.7
Delaware	124,055	48.9	49.4	30.4	67.9
District of Columbia	44,150	38.3	33.4	19.2	52.5
Florida	1,727,136	43.6	34.2	20.7	57.1

Source: CDC, 2018

One reason patients cite regarding why they were not immunized is the lack of provider's recommendation on vaccination (Schneeberg et al., 2014). In order to attain the goal of increasing vaccinations rates, it is essential that providers were given the necessary tools to be effective in their job. Furthermore, for a change to sustain, a coordinated, multipronged adaptable change was required (Zimmerman, 2017). The Community Preventative Services Task Force (CPSTF) conducted a comprehensive literature review to determine ways to increase immunization uptake. Based on this study, increasing vaccinations included coordinated efforts and behavior changes from staff, patients and providers (CPSTF, 2014). The use of the *Four Pillars Immunization Toolkit* facilitated and supported the process in enhancing the vaccination uptake. The toolkit is a product that underwent years of research on the barriers and facilitators both from a patient and provider perspective (Zimmerman, 2017).

Purpose

The twofold purpose of this DNP project was to identify barriers faced by regional Arizona providers with respect to recommending appropriate pneumonia vaccines for patients 65 and older; and to increase pneumococcal vaccination rates for patients 65 and older in a single Arizona retail clinic by implementing the Four Pillars Immunization Toolkit.

To implement this toolkit, one clinic was identified to conduct this project and the Four Pillars on Immunization Toolkit was utilized. This project was done in coordination with the Department Head of Education of the Little Clinic and the Regional Director of Nursing services for Arizona.

Study Questions

The study questions for this quality improvement project aimed at answering the following:

1. Among Arizona regional providers in retail health clinic settings, what was the baseline knowledge and perception of barriers to pneumococcal vaccination of the providers?
2. What was the vaccination rate among eligible patients throughout four weeks of Four Pillars Immunization Toolkit implementation?

Synthesis of Evidence

Framework: The Stetler Model

The Stetler model (Stetler, 1994) was used as a vehicle to guide this project. This model, founded in 1976, is based on the principle of translating research into practice and could be used in an individual or group practice. Initially, the model did not have any basis in research, so it was focused on testing hypotheses. Since then, Stetler revised the model three times (1976, 1994,

2001), and it has been used in countless research studies on both the practitioner and organizational level. The current version of the model guides practitioners in assessing how research findings can be utilized in practice. The concept of the Stetler model is twofold: the translation of research into practice and the use of evidenced-based research to inform practice (National Collaborating Centre for Methods and Tools, 2010; Stetler, 2001). Regarding immunization, the decision of a patient to be immunized is dependent on the healthcare provider recommendation (Physician Weekly, 2015).

Model concepts as described by Stetler (2001) are composed of the following assumptions:

1. The formal organization may or may not be involved in an individual's research utilization.
2. Utilization may be instrumental, conceptual and symbolic.
3. Other types of evidence and non-research related information is likely to be combined with research findings to facilitate decision-making or problem solving.
4. Internal and external factors can influence an individual or a group's view and use of evidence.
5. Research and evaluation provide us with probabilistic information, not absolutes.
6. Lack of knowledge and skills about research utilization and evidenced-based practice (EBP) can inhibit appropriate effective use.

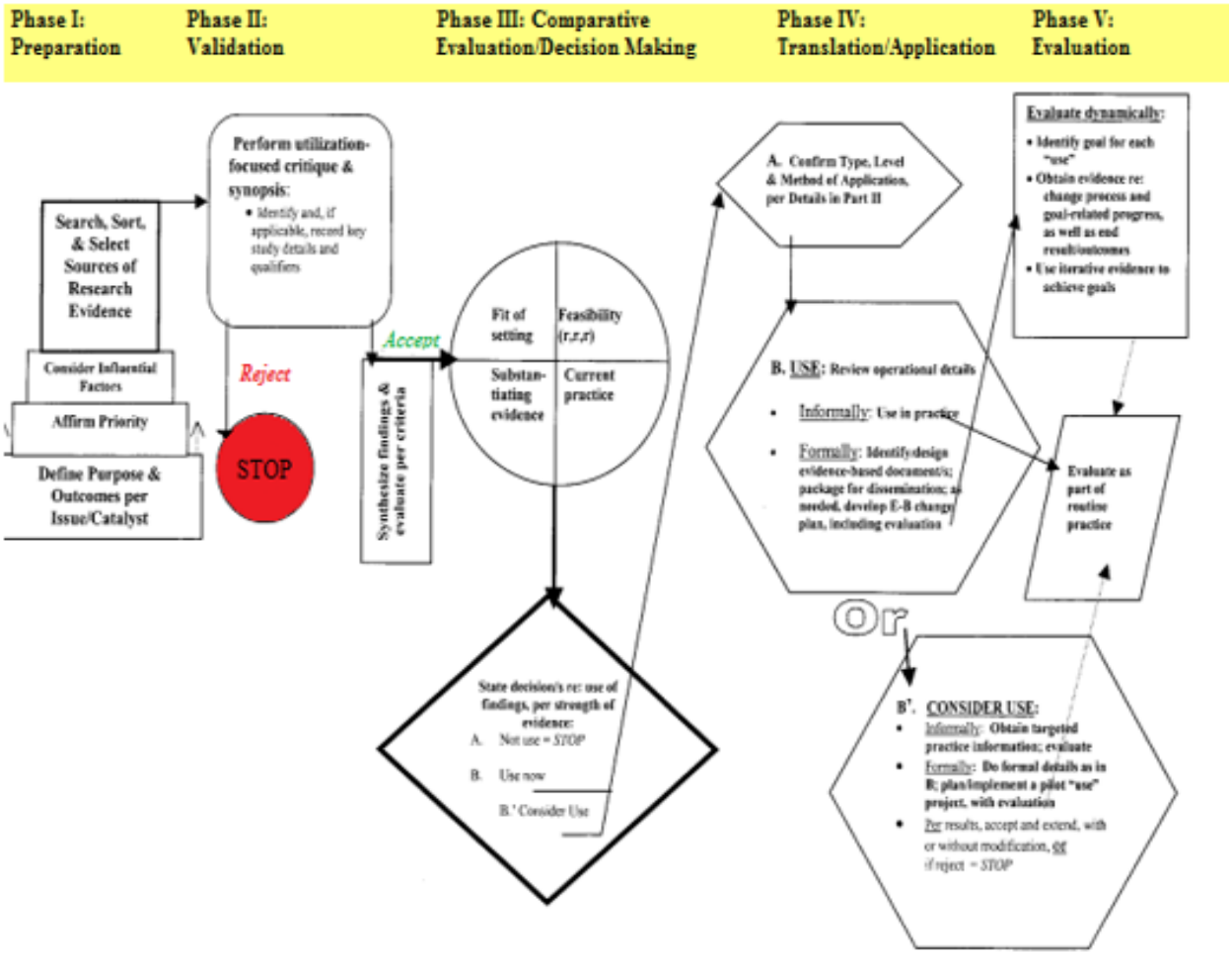


FIGURE 2. Stetler model, steps in research utilization to facilitate EBP. (Adapted from Stetler, C. 2001)

Phase I Preparation

Stetler (2001) described this phase as the phase where an individual practitioner identifies an issue (Figure 2). Included in this phase is the purpose, context, and research evidence (Figure 2). Activities included in this phase are identifying key stakeholders and consideration of other factors that can influence the research, which can be described as external or internal factors. For this DNP project, the pressing issue that the author identified was the low rate of pneumococcal vaccination among the adult population ages 65 years and older. The Healthy People 2020 goal

for pneumococcal vaccination is set at 90%. Currently, there is a nationwide attention on adult immunization as the vaccination rates for adults are substantially below the national goal (Tan, 2015).

The stakeholders for this study were identified as the following: Regional Director for the Little Clinic, Education Director for the Little Clinic, Providers and Patient Care Technicians. One factor that may affect this study is the setting of this project. Unlike primary care offices, the retail-based clinic is a walk-in clinic. The provider might not be familiar with the patients as compared to a primary care office, and time might be a factor to consider in this setting.

Phase II Validation

The second phase of this model investigates the quality of existing evidence within the literature (Stetler, 2001). Currently, the literature has many resources on the use of Pneumovax 23 (PPSV23) and Prevnar 13 (PCV13). The pieces of evidence provided were randomized controlled trials, systematic reviews, and meta-analyses on vaccine effectiveness. These pieces of evidence showed vaccine effectiveness of pneumococcal vaccines. One of the many examples is the Community-Acquired Pneumonia Trial in Adults on the use of PCV13 (CAPiTA). This trial is the largest randomized controlled trial in adults on the use of PCV13 against pneumonia. Based on the results of CAPiTA, the ACIP recommended routine sequential administration of PCV13 and PPSV23 in September 2014 (Isturiz & Webber, 2015).

Phase III Comparative Evaluation and Decision Making

Stetler (2001) describes this phase as a comparative evaluation and decision-making phase. Included in this phase are four criteria to determine if the research can be applied to the practice. The first criterion is the synthesis of findings. Considering previous evidence presented

on the effectiveness of PPSV23 and PCV13 vaccines, the researcher concludes that it is advisable to promote the pneumococcal vaccination. The second criterion evaluates the degree of feasibility, including consideration of risk, resources, and readiness. The company where this project occurred advocates the use of evidenced -based practice; therefore, it is not hard to get the support of the management as the company advocates the development of projects that can improve the delivery of health care in this setting. The third and fourth criteria include comparing the evidence with the current practice. The clinic has the availability of the vaccinations; however, the uptake for the pneumonia vaccines remains lower and trails behind other vaccines.

Phase IV Translation/Application

Stetler (2001) describes this phase as the translation and application phase. It involves the implementation of the research findings, which can be formal or informal. One should also consider the level where this evidence will be implemented: individual or group. This phase also considers the formal dissemination, which can be delivered through strategies such as appointing vaccine champions, providing interactive education, or conducting educational outreach.

Phase V Evaluation

Stetler (2001) describes this phase as the evaluation phase. The clinician at this phase evaluates the findings and considers the direct use of the evidence. If the practitioner decides to make direct use of the evidence, there needs to be pilot testing with a small group of people to consider feasibility for a larger group of people. The project yielded a favorable result on immunization rates. The process can be presented to the management to integrate in the current practice.

Conceptual Terms

The focus of this quality improvement (QI) project was to address the immunization status of patients 65 years and older who use retail health clinics in Arizona. Among the population 65 years and older, inherent in this population is the use of Medicare insurance. The Medicare insurance program created in 1965 is a federal health insurance program for people aged 65 or older. In 1972, the program was expanded to cover certain people with disabilities and people with end stage renal disease (U.S. Centers for Medicaid and Medicare Services, n.d.). The setting for the QI project is The Little Clinic, which is also being referred to as a retail health clinic because is it located inside retail stores like Kroger, Fry's, JC, Dillon's, King Scoopers and Kroger stores (locally known as Fry's). The Little Clinic employs practitioners such as physician assistants or nurse practitioners. Open seven days a week, the clinic offers an alternative treatment to receive care outside the operating hours of primary care doctors, giving patients the benefits of ease of access and cost-effective methods for receiving care (Heath, 2017). There are approximately 215 Little Clinics across the United States. In Arizona alone, there are 16 clinics located across Arizona (The Little Clinic, 2019).

Currently, the Little Clinic is participating in the Merit-based Incentive Payment System (MIPS) quality measure data. MIPS was created to improve the health of all Americans by providing incentives to improve health outcomes (Manchikanti, Helm, Benyamin, & Hirsch, 2016). One of the measures that the Little Clinic is using is the pneumococcal vaccination.

The end goal of the QI project is the increase of pneumococcal vaccination for patients 65 years old and older. There are two types of pneumococcal vaccination licensed for use in the United States by the Food Drug Administration (FDA): *Pneumococcal conjugate vaccine* known

as *Prevnar 13* (PCV13) and *23 Pneumococcal polysaccharide vaccine* known as *Pneumovax 23* (PPSV23).

Prevnar 13 vaccine helps protect against 13 types of pneumococcal bacteria. It can prevent ear infections and pneumonia caused by those 13 types. This vaccine is given to children at ages 2 months, 4 months, 6 months, and 12 through 15 months. This vaccine is also indicated for older children and adults who are at increased risk for getting pneumococcal disease. For adults who need the vaccine, it is only given once (CDC, 2017). Prevnar 13 is a pneumococcal conjugate vaccine; conjugate refers to the type of vaccine that joins a protein to the part bacteria (CDC, 2017). *Pneumovax 23* protects against serious infections caused by 23 types of pneumococcal bacteria. This vaccine is given as a single dose or sometimes includes one or two additional doses for people with a particular chronic medical condition. It is approved to be administered to people aged 2 years and older and 50 years of age and older who are at increased risk for pneumococcal disease (CDC, 2017). Pneumovax 23 is a pneumococcal polysaccharide vaccine; polysaccharide refers to the type of vaccine that mimics the appearance of certain bacteria (CDC, 2018).

The Four Pillars Immunization Toolkit is an approach to adult immunization that utilizes four strategies. Developed by the University of Pittsburg, this strategy includes a step-by-step guide in delivering vaccination in an outpatient setting. The four strategies included in this approach are called pillars. Pillar 1 consists of offering convenient vaccine locations. Pillar 2 consists of conveying to patients the importance of the vaccine and the availability of the vaccine. Pillar 3 includes enhancing the way the clinic offers immunization and Pillar 4 is the motivation of the staff to engage in the vaccination practices through identifying a champion in

the clinic. Furthermore, the Four Pillars Immunization Toolkit includes identification of barriers to increasing vaccination and the importance of giving a vaccine that can prevent illnesses (University of Pittsburg, 2019).

Literature Review

With the aging population, the economic burden of pneumococcal infection continues to affect everyone. Vaccines are not used to prevent diseases only for young children, but also for adults who are at risk for illnesses, hospitalizations, and even vaccine-preventable deaths. Despite the efforts placed on adult immunization, the 90% adult immunization goal for Healthy People 2020 has not been realized. Current data shows that 40,000-50,000 die from vaccine-preventable diseases every year (Terrie, 2019). Although vaccines have been proven to have an enormous positive impact on health, many do not adhere with vaccination recommendations (Tan, 2015). Several reasons were identified for low adherence, such as noncompliance of adults, giving the vaccine a low priority both by the patient and the provider, lack of information regarding a vaccine, fear and opposition of the vaccine, affordability, and hindrances such as access to vaccines and systemic barriers (Wick, 2013).

To establish the efficacy of vaccines, understand barriers that affect successful vaccination programs, and provide ways to implement a vaccination program that can increase the vaccination rates of pneumonia vaccines, several literature searches were conducted using PubMed, Cumulative Index of Nursing and Allied Health Literature (CINAHL), EBSCOhost, and Google Scholar. The following keywords were utilized in searching the databases: pneumococcal vaccinations, PPSV23, PCV13, patients 65 years and older, vaccination barriers, and retail clinics. Inclusion criteria for articles are those that were published within the last five

years, limited to English, and discussed human subjects who were 65 years and older. Articles that did not meet the criteria on pneumonia vaccination were eliminated from the study. Nine articles were chosen for this study. The articles used in the review of evidence included a variety of research approaches: randomized controlled trials, systematic reviews and meta-analyses, surveys, mixed methods, and cross-sectional designs.

A very recent study (McLaughlin et al., 2019) used a cross-sectional design to establish the demographics and characteristics of patients who were most unlikely to get the pneumonia vaccination. It also measured the proportion of adults who were vaccinated against PCV13 following the recommendations of ACIP. Giving credence to the study, the sample population is a large population base composed of 8,133,847 participants gathered from office-based medical claims, pharmacy, and hospital-based charge master claim databases. The outcome of this study noted that there was increased uptake of PCV13 among patients 65 years old and older. The demographic characteristics of people with poor adherence to vaccine recommendations includes people from poor minority communities, rural areas, and with low educational attainment. These same populations are at increased risk for pneumococcal infection. This finding established the need for providers to offer vaccinations to these groups of people.

Another cross-sectional study (Schneeberg et al., 2014) sought to understand the factors influencing pneumococcal vaccination among older adults in Canada. Inclusion criteria included living independently and requiring minimal support for activities of daily living in five cities in Canada. The findings noted that physicians' knowledge of vaccination affects whether they recommend it to patients. The study also validated that a physicians' recommendation is consistently found to be an independent predictor for pneumonia vaccination. Hence, it is

essential that providers be equipped with adequate knowledge on vaccinations in order to educate patients on their need for vaccination. This finding is consistent with the study by Hurley et al. (2018), which was an assessment survey conducted among physicians on the knowledge gaps and barriers in recommending pneumococcal vaccination. It was noted that 50% of the physicians were unclear about the current pneumococcal guideline. Additionally, about one-third or more gave an incorrect dosing interval of PCV13 and PPSV23. Without knowledge-based recommendations, pneumococcal vaccination cannot be implemented.

Studies by Falkenhorst et al. (2017) and Botten et al. (2015) established the efficacy of the Pneumovax 23 and Prevnar 13 vaccines. Falkenhorst et al. (2017) pooled 17 eligible studies for a systematic review and meta-analysis looking for the effectiveness of Pneumovax 23. In four clinical trials, the vaccine effectiveness was 73%, while in three cohort studies vaccine effectiveness was at 45%, and in three case-control studies, vaccine effectiveness was at 59%. Overall, the meta-analysis revealed significant vaccine effectiveness of Pneumovax 23 against invasive pneumococcal disease and pneumococcal pneumonia in the elderly.

The Community-Acquired Pneumonia Immunization Trial in Adults (CAPiTA) study on the prevention of adult pneumococcal pneumonia with PCV13 (Bonten et al., 2015) was a randomized controlled trial of adults > 65 years of age. This study found statistically significant vaccine efficacy for first episodes of vaccine-type community-acquired pneumonia (46%), nonbacteremic/noninvasive vaccine type (45%), and vaccine-type invasive pneumococcal disease (75%). This study also reviewed the safety profile of Prevnar 13 showing that Prevnar 13 is safe to use and has a well-established safety profile.

The literature search revealed there is a gap in the use of retail clinics to administer vaccinations. Retail clinics are scattered across the United States and are located in easily accessible areas with convenient extended hours. Despite the increased accessibility, few studies examined vaccination practices in the retail health clinics. Uscher-Pines et al. (2012) conducted a qualitative study on retail clinics as a venue to promote and administer vaccinations. The study sample was the three largest retail clinics in the country: Minute Clinic, Take Care Clinic and The Little Clinic. Across these three clinics, there were 8.9 million visits with 1.8 million influenza vaccinations given and 59,849 pneumococcal vaccinations administered from 2007-2009. In comparing the yearly data, results reveal a yearly increase in the vaccination rates at 39.9%, 36.4% and 42%. This data shows that the retail-based health clinics can be an avenue to capture immunizations among adults; however, providers have to be intentional to capture this during the visit (Uscher-Pines et al., 2012). The study is consistent with another study of a retail clinic by Duong (2016) examining a vaccination PCV13 protocol in the Palomar retail clinic. A total of 155 patients were deemed eligible for the study. This descriptive study utilized the *Proves Discrepancy Evaluation Model*. The providers were educated on the need for pneumonia vaccination. Providers increased their vaccine recommendations, which resulted in increased vaccination of the patients. In the three months that the researcher implemented the study, there was an increase in pneumonia vaccination to 2.5%, 20.9% and 14.3% from the baseline. Overall, the outcome of the study showed increased vaccination rates after education of providers on the pneumonia vaccine.

There were various studies conducted on the use of the Four Pillars Immunization Toolkit. A randomized control study conducted by Zimmerman et al. (2017), on the use of the

toolkit to increase pneumococcal vaccination for older adults showed significant improvement for 23-valent pneumococcal polysaccharide vaccine (PPSV23) and pneumococcal conjugate vaccine .This study identified 25 primary care practices with a cohort of 18,702 patients 65 years and older with a mean age of 74.2

METHODS

Research Questions

This QI project consisted firstly of assessing the baseline knowledge of Arizona regional providers about pneumococcal vaccinations and on barriers to pneumococcal vaccination. The second part of the study was the utilization of the Four Pillars on Immunization Toolkit to increase pneumonia vaccination rates in that same setting.

Design

A descriptive cross-sectional study was conducted in the form of a survey to assess baseline knowledge and to identify perceived barriers to vaccine administration among providers. The survey questionnaire was patterned after another survey (Hurley et al., 2018) developed in coordination with the CDC. In this survey, each provider was given a series of seven case scenarios. The scenarios were created to determine the knowledge of the providers based on the ACIP recommendations. In addition, a series of five questions were developed in coordination with a clinical expert to assess the providers' perceptions regarding barriers in giving vaccines. In order to address the second study question, a prospective observational study was conducted during four weeks of Four Pillars Immunization Toolkit implementation in one of the retail clinic locations in Arizona.

Ethical Considerations

Before the implementation of this project, an Institutional Review Board approval through the University of Arizona (IRB) was obtained (Appendix A). The Director of Education for the retail clinic also approved the project before the implementation. Prior to the survey, participating providers gave their consent. Participation was voluntary, and no incentives were offered. Anonymity and confidentiality were assured to participants. The participants could stop at any time during the survey without any consequences. The data gathered for this project include de-identified data on how many patients 65 years old and older presented to the clinic, how many had immunization in the past and how many were given the immunization.

For the Four Pillars on Immunization Toolkit implementation, one site was chosen for the implementation of this project. This clinic site consisted of four full time staff members. All participants gave their consent before the implementation of the project. The data gathered for this part of the project included identified data on how many patients who were 65 years and older presented to the clinic, how many had the immunization in the past and how many patients were given the immunization.

Setting and Participants

The data for the survey were collected from healthcare providers working for retail health care clinics in Arizona. The retail clinics were located inside grocery stores, which were owned and operated by a corporation. There were 16 clinics in different locations and each clinic was staffed with two full-time providers along with per diem or float providers. The providers were either nurse practitioners or physician assistants. Two nurse practitioners who were designated as Regional Clinical Directors oversaw the Arizona retail clinics.

The inclusion criteria for the survey included (a) nurse practitioners or physician assistants (b) working and providing treatment to patients seen at the retail location. A survey link was sent to potential participants through their work email. Two survey reminders were also sent, one at the end of the first week and another at the end of the second week. Participants were assured of confidentiality and anonymity. There were no identifying data obtained and only aggregate data was shared.

The second part of the project was the utilization of the Four Pillars on Immunization Toolkit to increase the pneumococcal vaccination rates. One site was chosen for the implementation of this project. There were four full time staff in this location consisting of one nurse practitioner, one physician assistant and two patient care technicians (PCTs). The staff had a set work schedule and was divided into two teams. On some occasions when a full-time provider had taken time off from work, a float provider, who worked in different clinics, also worked in this location. This retail clinic is contracted with most of the commercial insurances including Medicare and Medicaid insurances. Most of the patients were walk-in customers; however, recently patients became able to schedule a same day visit ahead of time. While this clinic offered Pneumovax 23 and Prevnar 13 vaccinations, the uptake remained low. For example, last year from September 1, 2018 to October 1, 2018, the vaccination rates for these two vaccines was zero.

Prior to the initiation of the project, coordination with the Head of Education for the retail health care clinic was done. After the approval of this project, the Regional Clinical Director was also informed and agreed to support the project. An IRB approval was obtained as well. The initiation of the project started with a lunch meeting with the staff of the chosen site. A 30-

minute PowerPoint presentation was conducted with time for questions and answers provided. The project implementation ran from September 6, 2019 to October 6, 2019. A vaccination champion, who volunteered their services, were identified for each team. The vaccination champion was expected to make sure that there were available vaccines in the clinic and to track the quantity of immunizations given for each week. A tracking system was developed to document how many Prevnar 13 and Pneumovax 23 were given each week.

As part of the toolkit implementation, a pneumococcal poster (Appendix E) was placed in strategic areas where patients could easily view it. When a 65-year-old patient checked in, the PCTs administered the questionnaires "What Vaccine Do I Need?" (Appendix F) and "Vaccine Information System" (Appendix G). Once the provider saw the patient, the provider discussed the vaccine with the patient and recorded in the Electronic Medical Record (EMR) if the patient had received the vaccine in the past and if the patient was interested in getting the vaccine. The providers were given the option to use the guides "Vaccine Schedule" (Appendix H) and "Vaccine Timing" (Appendix I) to help in the decision on what vaccine should be given.

Data Collection

For the question on assessing the baseline knowledge of the providers on the current pneumococcal vaccination, the data was collected through a survey. The survey consisted of questions including seven knowledge questions, three demographics questions, and five questions on perceived barriers to administering vaccinations. A Qualtrics link to the survey was sent to the participants' work email (Appendix D). It was estimated that the survey took less than 10 minutes. The participants gave their consent prior to the survey and could stop at any time. These data did not include any identifiers or, were de-identified prior to analysis.

The data collection for the assessment of vaccination rates during the toolkit implementation period involved coordinating with the Information Technology department from the headquarters. Patients 65 years and older were identified and past records were sought to determine vaccination history. All patients eligible to receive a pneumococcal vaccination based on Toolkit guidelines were included in analysis.

Data Analysis

Based on survey questions used in assessing the provider's knowledge on baseline pneumococcal vaccination rate, data analysis including descriptive statistics in the form of counts and percentages was done using Qualtrics and Microsoft Excel 2016. The data are presented in a table and graph formats (Table 4). The data for vaccination rates during the utilization of the toolkit are presented in a table and graph formats (Table 5 & 6).

RESULTS

Sample Demographics

The survey was sent to 44 nurse practitioner and physician assistants. Out of the total 44 participants, 36 participants completed the demographic survey. Most providers had 0 to 4 years of experience and family practice experience. Table 3 shows the demographic characteristics of the participants.

TABLE 3. *Self-reported demographic characteristics of the participants.*

Demographic Characteristics	Category	% n=36
Gender	Male	5 (14%)
	Female	31 (86%)
Years in Practice	0-4	17 (47%)
	5-10	6 (17%)
	11-15	6 (17%)
	> 15	7 (19%)
Experience in Other Specialty*	Family Practice	24 (67%)
	Urgent Care/ER	11 (31%)
	Others	8 (22%)

*Specialty categories are not mutually exclusive, and thus do not total 36 (100%)

Provider Knowledge of Adult Pneumococcal Vaccine

The providers were given a series of questions to determine their baseline knowledge of pneumonia vaccination. Out of the 36 providers who completed the demographic survey, 33 providers answered the knowledge and perception question. The questions were presented with a multiple-choice answer. One of the options given was the “I need to look this up” answer. The data analysis shows that 81% of providers were able to identify which vaccine is to be administered first to patients ≥ 65 years old (Table 4). The second-highest score obtained was for the dosing interval between Prevnar 13 and Pneumovax 23 in patients ≥ 65 years old with 79% of the providers answering correctly. Regarding patients under age 65 with a qualifying condition, only 15% knew the correct dosing interval between PCV13 and PPSV23, which was also the lowest correct score on the knowledge survey. For this question, 61% chose incorrect responses rather than choosing option of “I need to look this up.” Suggesting confidence in their current vaccination knowledge even if incorrect. This data suggests that providers were most knowledgeable on the dosing interval in patients 65 years of age or older, but less knowledgeable on the dosing interval in patients less than 65 years old.

The second-lowest correct score (27%) was on the knowledge questions was which vaccine should be given to patients under the age of 65 with asthma, a chronic illness. In comparison, providers were most knowledgeable of which vaccine to give to patients 65 years old or older, who have a chronic illness.

The question garnering the highest percentage of responses where provider would need to research the answer was on the dosing interval for Pneumovax 23 for patients ≥ aged 65 who received a previous dose of the same prior to age 65. Some 30% of the providers opted “I would need to look this up” and 33% chose incorrect responses, so although providers were aware of the first vaccine that needs to be given to patients ≥ age 65, providers were not completely knowledgeable regarding PPSV23 dosing regimens affecting this age group.

In general, the mean score for the correct responses was 44.42, while the mean score for incorrect responses was 28.28. These means indicate that providers are knowledgeable on the topic to some degree, but a knowledge gap still exists.

TABLE 4. *Number of participants answering the knowledge question*

Knowledge Concept	Correct	Incorrect	Need to look up
Dosing Interval for PPSV 23 when a patient received PPSV23 at <65. When is the next due PPSV 23 due? (*Chronic heart disease)*	12	11	10
In patients with qualifying condition, what is the interval dosing between the PCV 13 and PPSV 23? (*Cochlear Implant)*	5	20	8
Dosing Interval between PCV 13 and PPSV 23 in a 67-year-old patient (*HTN needed refill)*	26	4	3
Which pneumonia vaccine should be given first to adults ≥ 65? (*Annual Wellness)*	26	3	3
What vaccine is needed for a 24-year -old patient? (*Asthma Pt)*	9	16	8
In 28-year-old patients with qualifying condition who received PPSV 23 a year ago, what vaccine does she need? *(HIV*)	20	9	4
What pneumonia vaccine should be received first in a 42 -year-old patients with qualifying condition? (*Nephrotic Syndrome)*	14	10	9

PPSV (Pneumovax 23)

PCV13(Prevnar 13

Perception of Barriers

Data analysis on the barriers to giving pneumonia vaccines to patients 65 years old and older showed that participants felt that this is not a significant barrier (Figure 3). Most of the participants were aware of what vaccines were needed for patients age 65 and older with a percentage of 67% (about 22 participants). However, about 6% (2 participants) answered the question that major barriers exist. This data shows that many of the providers understand what vaccines are needed for patients over the age of 65. This data has linear relationships with the knowledge question on what vaccine should be given to patients 65 years and older. Because providers were knowledgeable, 81% got the correct answer; the providers therefore do not consider any barrier in giving immunization to this age group.

Level of Severity

The data showed that the question targeting the level of severity warranting Pneumovax 23 was distributed among the different categories (Figure 3). About 38% (12 participants) answered that this is not a barrier. However, almost the same number of participants, 34% (11 participants), considered this as a minor barrier. About 22% (7 participants) answered this question as a moderate barrier. Very few providers (6%) considered this as a major barrier. This category indicates that the participant's perception varies in this category.

Dosing intervals between Prevnar 13 and Pnuemovax 23 ≥ 65 years old. Data analysis indicated most of the providers at 63% or 20 participants (Figure 3) indicated that they do not consider the dosing interval between Prevnar 13 and Pneumovax 23 as a barrier. Two participants consider this as a major barrier. There were 16% or five participants who considers this as either a moderate or a minor barrier. In comparing this to the knowledge on the 67-year-old patient with hypertension who needed medication refill, the participants also scored 79% or 26 providers answered this category correctly. This score was one of the highest scores obtained among all the knowledge questions confirming that participants are comfortable and knowledgeable in this category.

Unaware Patients and Vaccines

This analysis indicates patients are unaware of what previous vaccines they received; the unawareness will create a barrier in receiving the next vaccine (Figure 3). About 42%, or 13 participants, considered this as a major barrier. Among all the perceived barriers, this condition obtained the highest rating as a major barrier in giving or recommending the pneumonia vaccination. This data indicated the general findings on the perception of barriers show that unawareness of what vaccine the patient had is a significant barrier in giving the pneumonia vaccine in a retail setting.

Barrier perception on medical condition that warrants both Prevnar 13 and Pneumovax 23 for patients 65 years and under. Figure 3 shows that 33% or 11 of the respondents consider this category on medical conditions warranting both Pneumovax 23 and Prevnar 13 as a moderate barrier, while 30% or 10 of the participants consider this as a minor barrier. There were 24% or eight of the providers who considered this category not as a barrier,

while 9% or three of the participants considered this as a major barrier. One of the participants selected the answer of not sure.

In general, the data indicated that the participants' responses varied, but indicated that knowledge deficits exist.

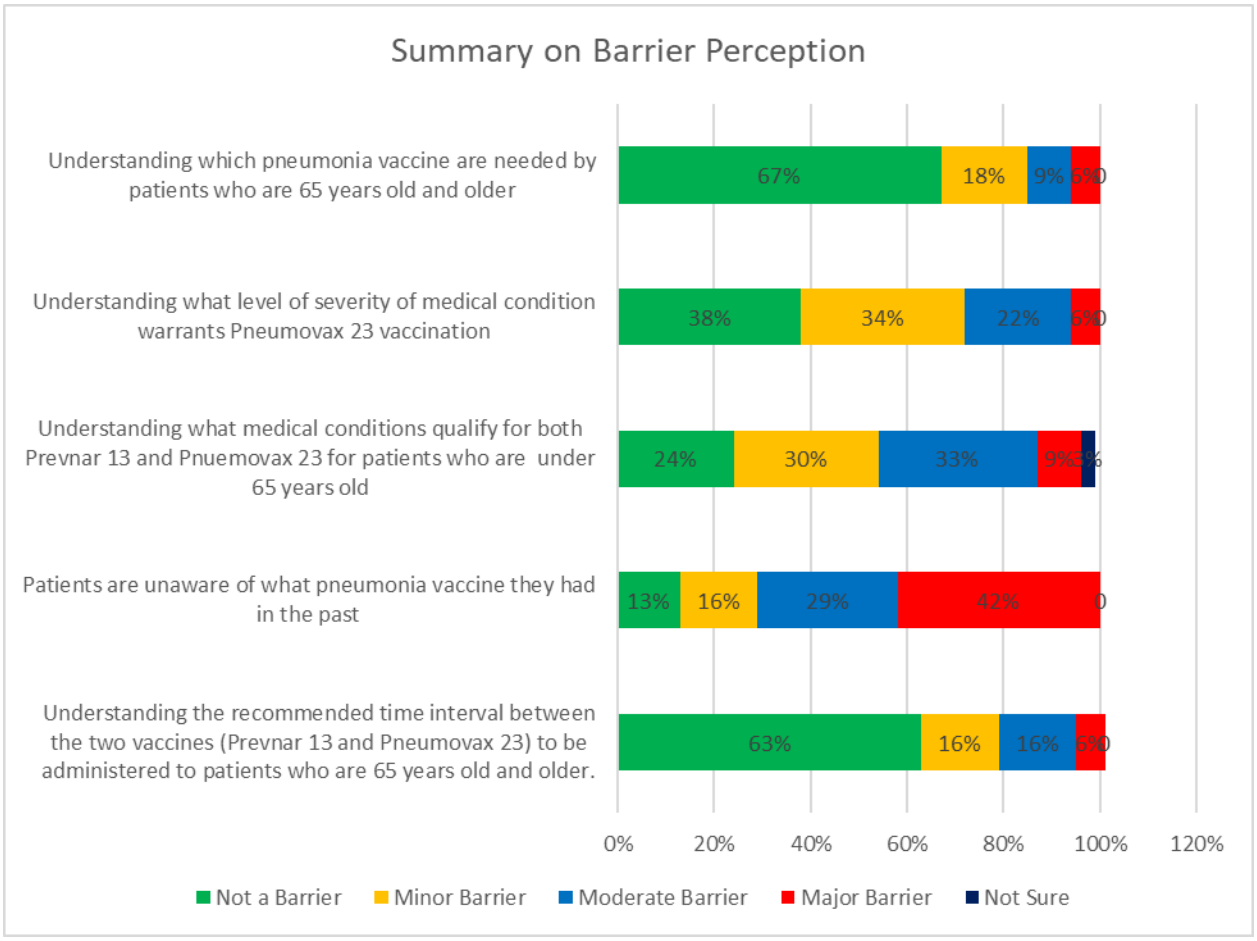


FIGURE 3. Summary on barrier perception.

Data on Utilizing the Four Pillars on Immunization Toolkit

The Four Pillars on Immunization toolkit was utilized in one of the clinics in Arizona Region. This toolkit was implemented from September 6, 2019 to October 6, 2019. Data were gathered to determine if using the toolkit will result in an increase in vaccination rate for

pneumonia vaccine among patients 65 years and older. The data analysis was for a one-month period from September 6, 2019 to October 6, 2019 (Table 5). These patients were qualified to receive either Prevnar 13 or Pneumovax 23. The total number of patients seen within this period was 546 patients. Out of this total number of patients, 22 patients were older or equal to 65 years of age as a patient. Some 20 patients were eligible for the pneumonia vaccine. The rest of the patients' ages were below 65 years old.

TABLE 5. *Summary of eligible patients seen and received vaccination.*

Week	**Total Pts Seen**	**Patients ≥65**	**Number Eligible**	**Number Vaccinated**
Week 1	144	6	6	0
Week 2	88	1	1	0
Week 3	177	8	7	1
Week 4	197	7	6	1

Uptake on Prevnar 13 and Pneumovax 23

The data shows 22 patients were older than 65 years of age who presented to the clinic during the study period (Table 6). The length of the study was one month. Of the 22 patients, two patients in week 1 and week 2 already received their immunization series somewhere else, thus, making the total eligible patients seen in the clinic at 20. During the study period, one patient was vaccinated with Prevnar 1, and one patient was vaccinated with Pneumovax 23.

TABLE 6. *Summary of patients seen and number vaccinated.*

Sum	Total Patients ≥65	Total Immunized	Prevnar 13	Pneumovax 23
Total	20	2	1	1

DISCUSSION

There are two parts to this project. The first part of the project was to assess the providers' baseline knowledge and perception of barriers in giving pneumococcal vaccinations. The second part was to implement the toolkit in providing pneumococcal vaccinations to patients age 65 and older in a retail clinic setting.

Knowledge and Perception

There were several knowledge gaps noted from responses to the knowledge questionnaire. Most participants, however, were able to answer correctly the question of which is the first immunization to be given to patients who were ≥65 years old with no history of prior vaccination. The provider's knowledge in this area could have been related to media campaigns on immunization targeting seniors. Most of the providers also answered the dosing interval between Pneumovax 23 and PCV13 for patients ≥ 65 years old correctly. In comparison, there seems to be a knowledge gap regarding the dosing interval between Pneumovax 23 and Prevnar 13 for patients under age 65. Only 15% of the participants answered this question correctly. In addition, 48% of the participants answered incorrectly the question about what type of vaccine an asthmatic patient 65 years old and below old should receive. Only 36% of the providers knew the correct dosing interval when Pneumovax 23 is given to patients ≥ 65 years old after a prior dose before age 65, revealing another knowledge gap. In general, the highest scores obtained were for those vaccines targeting the seniors, but a lowered score noted to those vaccines targeting patients below 65 years old. The results of this survey will be sent to the management with suggestions on interventions to address the issue.

The perception on barriers to giving pneumococcal vaccination in a retail health setting is varied. The highest score obtained from the data set (42%) in this section was the difficulty determining what vaccines the patients previously received. Patients are unaware of what previous vaccine they had received. The lack of record keeping for pneumonia vaccine can be attributed to this scenario of patients getting their pneumonia vaccines from different providers ranging from their doctor's office, to retail clinics, or local pharmacies. When a patient does not have a record of their vaccine, it is difficult to determine which immunization to give. Adult patients who do not have any immunization records that they can show to the provider is a missed opportunity to vaccinate.

Several implications can be made from this study, for example, the need to address the knowledge deficits of the providers. Some of the strategies that can be implemented to address this need is the provision of the vaccine timing guide from the CDC be given to each clinic. In addition, an education campaign targeting pneumonia vaccinations should be created through a platform such as the HealthStream. The HealthStream is the platform the Little Clinic uses for education dissemination.

Another approach that might help the providers in the decision-making process of what vaccine to give is the creation of a Clinical Support Decision System (CDSS) within the Electronic Medical Record (EMR) to identify adult patients needing pneumonia vaccination. Rather than relying on the knowledge of the provider, the CDSS can help providers make decisions.

There is also a need to create a Nationwide Adult Vaccination System that providers can access to determine what vaccine the patient has already received. This strategy would most

likely address the highest-rated barrier on patients being unaware of what vaccine they already received. This strategy will take longer to implement. A short-term solution to utilize is the vaccine passbook that can be given to patients. This vaccine passbook will contain immunization records that patients can bring during their appointments.

On Toolkit Utilization

Data shows immunization coverage for pneumonia vaccination is below the goal of Healthy People 2020 (CDC, 2015). The national target for Healthy People 2020 for pneumonia vaccination is at 90%. The actual vaccination rates for patients with high-risk conditions between 19-64 years old is at 21% and the national percentage for pneumonia vaccine for adults greater than or equal to 65 years and older is at 60% (CDC, 2015). To see if a retail clinic can be used as an avenue to increase the pneumococcal vaccination rate, the Four Pillars on Immunization Toolkit project was utilized and implemented in a retail clinic setting. The findings showed when compared to last year's data (2018) on the pneumonia vaccination rate at the 91st and Olive Little Clinic; there is an increase of 10% pneumonia vaccination rate with the utilization of the Four Pillars on Immunization Toolkit.

Retail health clinics can be avenues to close the gap in vaccination rates through the growing number of retail clinics across the country. These clinics provide convenient locations, easy access to care, convenient hours, and walk-in visits with prices that are transparent (Kaiisi, 2015). In addition, to be competitive at the local market, scheduled appointments are utilized.

The missed vaccination data where patients were unaware of what vaccine they had in the past or did not get their pneumonia immunization because of no vaccine record represents a significant opportunity to provide patients with a vital vaccine. CDC (2016) guidelines about

revaccination for those over the age of 65 who are unaware of what vaccine they had in the past can be summarized with the following questions: Has the person been vaccinated previously? No or unsure answer, give the vaccine.

On the first two weeks of the project implementation, there were no vaccines given as this was expected due to a learning curve for the providers. In the third and fourth weeks, there were 85.7% and 87.5% eligible patients who were identified and out of these eligible patients, two were vaccinated. These results most likely reflect the provider's comfort level with the project. In addition, there was a slight increase in patients over or equal to 65 years of age who were seen in the clinic secondary to the availability of the influenza vaccine.

There were several barriers that the providers discussed and mentioned during the period of this study. For example, the Electronic Medical Record (EMR) does not prompt providers to ask questions on immunization and at times due to the volume of patients, they often forget to ask or mention the pneumonia vaccine. Another issue reported by the providers was that of patients not knowing what vaccines they had in the past, which prompted the providers not to give or recommend a vaccine because insurance may not cover the service. This may lead to the patients paying out of their pockets. In addition, there was one occasion where the patient was ready to get the vaccine, however the clinic ran out of Prevnar 13. There was also an instance where a float provider who is not aware of the project worked in the clinic for just a single day.

Another barrier that can be deduced from this project is the continued emphasis on acute illnesses versus preventative care. For the immunization vaccination rate to increase in this setting, there should be a continued effort to educate providers on preventative measures such as immunization practices. In addition, the Electronic Medical Record (EMR) should be enhanced

to prompt providers to ask immunization questions rather than rely solely on the providers to remember to ask the patients. While this project was conducted in a short period of time, with few patients getting vaccinated, it does support retail health clinics as avenues to increase Pneumonia vaccination rates as well as help achieve the Healthy People Goal 2020 and beyond.

Limitations and Conclusion

Knowledge of the provider and the perception of barriers to Pneumonia vaccination was generated from a small sample size. Out of the possible 44 participants, 36 submitted their demographic survey. The participants were healthcare providers located in Arizona. No other locations outside of Arizona were asked to participate in the study. In utilizing the toolkit to increase the immunization, large sample sizes would have given a basis to determine if similar results would have been reproduced in other regions. Another limitation was the perception of barriers in pneumococcal vaccination. While content experts reviewed this, no previous analysis of the survey was done. In addition, the perceptions and knowledge of the providers may not be fully reproducible.

Study strengths include the Merit-based Incentive Payment System (MIPS), in which this retail clinic currently participates. The MIPS utilizes a data reporting system. Providers are required to document previous pneumonia vaccinations. This action compels the providers to inquire about pneumonia vaccine when a patient presents to the clinic. Although, the provider mentioned that although the documentation for the MIPS is required at times this is not always done. Significant findings included the knowledge gap of the providers and the barriers that the providers faced in recommending pneumonia vaccination.

The Four Pillars in Immunization Toolkit resulted in an increase in the vaccination rate when compared to the data from 2018. This can imply that though retail clinics are a newer form of health care delivery, vaccinations delivery can be employed in this setting. These findings validate how retail clinics could be used as avenues to help reach local and national immunization goals. The results of this study de-identified data will be shared with management.

The utilization of the Four Pillars on Immunization Toolkit also utilized a small sample size. Out of all the 16 total clinics, only one clinic was utilized for the study. Most of the visits in that location were patients below 65 years of age. The timing of the project is also taken into consideration. The clinic area is in the locality where older people are referred to as “snowbirds” and visit during the winter. This project was conducted at the time when it was too early for the “snowbirds” to come to Arizona and was only for a short duration of time. The survey conducted in this study uncovered a knowledge gap with the pneumococcal vaccination among the retail health providers. This study also showed there were significant barriers that the providers were facing regarding recommending or administering the pneumonia vaccine. There are very limited studies involving retail clinics specifically covering the topic of vaccination. This study is unique in the sense that retail clinics are growing in numbers; however, few researches has been done on the delivery of healthcare through this avenue. As the retail clinics continue to grow and expand its services, providers working in this area must ensure that the knowledge is current with the practice guidelines. Furthermore, this study also incorporated a toolkit through immunization practices. This toolkit showed that retail health clinics can assist in improving vaccination rates. The information gathered in this study may be applied to other retail sites who conduct a

pneumonia vaccination educational program and provide valuable resources, which providers can utilize.

APPENDIX A:

THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

Human Subjects Protection Program

1618 E. Helen St.
P.O.Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
http://rgw.arizona.edu/compliance/home

Date:	August 06, 2019
Principal Investigator:	Minnerva Estocado Carroz
Protocol Number:	1908864640
Protocol Title:	Increasing Pnuemococcal Vaccination Rates Among patients 65 years old and older in the Little Clinic and Assessing the baseline knowledge of the providers at the Little Clinic
Determination:	Human Subjects Review not Required

Documents Reviewed Concurrently:

HSPP Forms/Correspondence: *August IRB Determination form.pdf*

Regulatory Determinations/Comments:

- Not Research as defined by 45 CFR 46.102(l): As presented, the activities described above do not meet the definition of research cited in the regulations issued by U.S. Department of Health and Human Services which state that "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research."

The project listed above does not require oversight by the University of Arizona.

If the nature of the project changes, submit a new determination form to the Human Subjects Protection Program (HSPP) for reassessment. Changes include addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the study activity. Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

APPENDIX B:

RECRUITMENT LETTER

To the Little Clinic Healthcare Providers:

My name is Minnerva Carroz, MSN, FNP-C and I am a fellow retail clinic provider. I am currently completing my Doctor of Nursing Practice (DNP) degree at the University of Arizona. I am asking for your participation and assistance in my DNP project survey to assess the baseline pneumococcal vaccination knowledge in retail health care providers.

The current data on Pneumococcal vaccination rates for patients 65 years and older are way below the national goal, however retail clinics has been increasing in numbers. The retail clinics can be used as avenues to meet the Healthy People Goal for pneumonia vaccination. This survey will explore the needs and barriers of our providers in providing pneumococcal vaccinations as the retail clinic continue to expand beyond delivering acute care to providing preventative care. The purpose of this project is to assess provider baseline knowledge of pneumococcal vaccination in a retail setting.

There is a link for the online survey at the bottom of this email. This survey is estimated to take 10 minutes to complete.

There are no expected risks to participate in this project. Only aggregate data will be presented in a summary format. Your participation is voluntary. There are no consequences if you choose not to participate or if you choose not to complete the survey. Your participation is confidential and no identifying information will be collected.

Please email any questions or concerns you have regarding this project to me, the primary investigator at Mcarroz@email.arizona.edu. You may also contact me directly at 623-565-7563. I will do my best to respond to questions and concerns within 24 hours.

By completing the survey, you are consenting to participate in this research project and agree to have your de-identified responses used for this DNP quality improvement project.

https://uarizona.co1.qualtrics.com/jfe/form/SV_eaCbiyMNEH5cRAV

APPENDIX C:

RECRUITMENT LETTER UTILIZING THE FOUR PILLARS ON IMMUNIZATION

Increasing Pneumococcal Vaccination Rates Among 65 Year Old and Older Patients In A Retail Clinic Setting

by Minnerva Carroz

The purpose of this project is to increase vaccination pneumococcal rates among 65 years old and older patients utilizing the Four Pillars on Immunization Toolkit.

If you choose to take part in this project you will be asked to participate in the implementation of the toolkit. The toolkit involves making sure that pneumonia vaccines are available in the clinic, providing brochures, handouts to patients, asking about pneumonia vaccination status during the visit and the creation of a vaccination champion in the clinic. There are no foreseeable risks associated with participating in this project. You will receive no immediate benefit from your participation.

If you choose to participate in the project, your participation is voluntary and refusal to participate will involve no penalty or loss of benefits which you are otherwise entitled to. You may withdraw at any time from the project. In addition, you may skip any question that you choose not to answer. By participating, you do not give up any personal legal rights you may have as a participant.

For any questions, concerns, or complaints about the project, you may call Minnerva Carroz, FNP-C at 623 565 7563 and email address at mcarroz@email.arizona.edu

APPENDIX D:

SURVEY QUESTIONNAIRE

Survey questions

(Correct answers bolded and underlined)

1. **A 65-year-old, otherwise healthy woman with no history of prior pneumococcal vaccination, sees you for an Annual Wellness Visit. Which, if any, pneumococcal vaccine(s) should be administered <u>at this visit</u>?**

    - PPSV23
    - **<u>PCV13</u>**
    - None
    - ☐ Both
    - ☐ I would need to look this up

2. **A 24-year-old man sees you for a routine office visit. He has asthma and has not previously received any pneumococcal vaccines. Which, if any, pneumococcal vaccine(s) should be administered <u>at this visit</u>?**

    - **<u>PPSV23</u>**
    - PCV13
    - None
    - ☐ Both
    - ☐ I would need to look this up

3. **A 28-year-old woman with HIV infection sees you for a routine visit. She received 1 dose of PPSV23 one year ago. Which, if any, pneumococcal vaccine(s) should be administered <u>at this visit</u>?**

    - PPSV23
    - **<u>PCV13</u>**
    - None

☐ Both

☐ I would need to look this up

4. A 42-year-old man with nephrotic syndrome sees you for a routine visit. He has not previously received any pneumococcal vaccines. Which, if any, pneumococcal vaccine(s) should be administered <u>at this visit</u>?

- PPSV23
- **<u>PCV13</u>**
- None
- ☐ Both
- ☐ I would need to look this up

5. A 66-year-old man with chronic heart disease sees you for a routine visit. He received 1 dose of PPSV23 at age 64. At what age, if at all, should he receive another dose of PPSV23?

- Age 66
- Age 67
- **<u>Age 69</u>**
- Age 75
- I would need to look this up

6. A 42-year-old man with cochlear implants sees you for a routine visit. He had received a PCV13 vaccine at his otolaryngologist's office the day before. When should a PPSV23 vaccine be administered?

☐ Never. The patient does not need a PPSV23.

☐ **<u>At least 8 weeks after the PCV13 vaccine</u>**

- At least 1 year after the PCV13 vaccine

☐ At least 5 years after the PCV13 vaccine

☐ I would need to look this up

7. A 67-year-old man with hypertension presents for a medication refill. You notice he received a PCV13 vaccine 6 months ago, but has not received a PPSV23 vaccine. When should he receive the PPSV23 vaccine?

☐ Never. He does not need a PPSV23.

☐ Today

☐ **<u>In 6 months</u>**

☐ Five years after he received the PCV13 vaccine

☐ I would need to look this up

BARRIER QUESIONS

Do you consider the following as a barrier in recommending or giving the pneumonia vaccine to patients ?

1. **Understanding which Pneumococcal vaccines are needed by patients who are 65 years and older.**

☐Major Barrier ☐Moderate Barrier ☐ Minor Barrier ☐ Not a Barrier ☐ Not Sure

2. **Understanding the recommended time interval between the two vaccines (Prevnar 13 and Pnuemovax 23) to be administered to patients who are 65 years old and older.**

☐Major Barrier ☐Moderate Barrier ☐ Minor Barrier ☐ Not a Barrier ☐ Not Sure

3. **For patients who are under 65 years old with certain medical conditions, understanding what level of severity of medical condition warrants Pneumovax 23 vaccination.**

☐Major Barrier ☐Moderate Barrier ☐ Minor Barrier ☐ Not a Barrier ☐ Not Sure

4. **Patients are unaware of what kind of pnuemonia vaccine they had previously received.**

☐Major Barrier ☐Moderate Barrier ☐ Minor Barrier ☐ Not a Barrier ☐ Not Sure

5. **For patients under 65-years-old with certain medical , understanding the medication conditions that qualify a patient for both vaccines (Prevnar 13 and Pnuemovax 23)**

☐Major Barrier ☐Moderate Barrier ☐ Minor Barrier ☐ Not a Barrier ☐ Not Sure

APPENDIX E:

PNEUMOCOCCAL POSTER

Poster on Pneumococcal

Pneumococcal Disease

Hard to say it; easy to get vaccinated

What do *all* these people have in common?

Diane

Age 50
Heart Disease

Michael

Age 30
Asthma

Lily

Age 65
Healthy

Joseph

Age 55
Diabetes

They are all at increased risk for an infection called PNEUMOCOCCAL DISEASE

This deadly infection can strike quickly

Getting vaccinated is the safest, most effective way to protect yourself
If you are an adult with a chronic health condition like asthma, diabetes, or heart disease OR you are 65 or older, you are at risk

Ask about vaccination today

National Foundation for Infectious Diseases

This document is supported by an unrestricted educational grant from Pfizer Inc. The National Foundation for Infectious Diseases' (NFID) policies prohibit funders from controlling program content. To view NFID's policy for unrestricted educational grants, visit www.nfid.org/info/grantspolicy.pdf.

December 2012

APPENDIX F:

WHAT VACCINE DO I NEED?

Pneumococcal Disease:
Hard to say it; easy to get vaccinated

Integrating Vaccines for Adults Into Routine Care

Do You Need Pneumococcal Vaccination?

Pneumococcal disease is a very serious infection that causes pneumonia, meningitis, and bloodstream infection. There are vaccines that greatly reduce your chance of getting it.

To determine whether you may need pneumococcal vaccination, please check all that apply below. Even if you already had one vaccination, you may need another.

Check all that apply	✓YES
Are you 65 years or older?	
Do you have any of these diseases or medical conditions?	
Alcoholism	
Asthma	
Blood disorder (e.g., anemia, leukemia, sickle cell anemia, etc.)	
Cancer	
Cerebrospinal fluid (CSF) leaks	
Cochlear implants	
Diabetes	
Heart disease	
HIV/AIDS	
Immunodeficiency	
Kidney disease	
Liver disease	
Lung disease	
Solid organ transplant	
Spleen damaged, inactive or surgically absent	
Do you smoke cigarettes?	
Do you live or work at a long-term residential facility such as a nursing home?	
Have you ever received a pneumococcal vaccination or a 'pneumonia shot' in the past?	

If you checked any of the boxes above, your doctor may recommend that you be vaccinated against pneumococcal disease.

All adults should also receive an annual influenza vaccine to reduce risk of both flu and pneumococcal disease. Any adult who has never received a Tdap (tetanus, diphtheria, and pertussis or "whooping cough") vaccine should get one.

If you are age 60 or older, have other chronic health conditions, or are age 26 or younger, you may need additional vaccinations. For more information, visit **adultvaccination.org** or call us today.

Note for healthcare professionals: For more information, please refer to the Adult Pneumococcal Vaccination Guide for HCPs or visit: cdc.gov/vaccines/vpd-vac/pneumo.

National Foundation for Infectious Diseases

This initiative is supported by unrestricted educational grants from Merck and Co., Inc. and Pfizer Inc. NFID policies restrict funders from controlling program content.

October 2014

APPENDIX G:

VACCINE INFORMATION STATEMENT

VACCINE INFORMATION STATEMENT

VACCINE INFORMATION STATEMENT

Pneumococcal Polysaccharide Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Vaccination can protect older adults (and some children and younger adults) from **pneumococcal disease**.

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact. It can cause ear infections, and it can also lead to more serious infections of the:

- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain and spinal cord (meningitis). Meningitis can cause deafness and brain damage, and it can be fatal.

Anyone can get pneumococcal disease, but children under 2 years of age, people with certain medical conditions, adults over 65 years of age, and cigarette smokers are at the highest risk.

About 18,000 older adults die each year from pneumococcal disease in the United States.

Treatment of pneumococcal infections with penicillin and other drugs used to be more effective. But some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

2 Pneumococcal polysaccharide vaccine (PPSV23)

Pneumococcal polysaccharide vaccine (PPSV23) protects against 23 types of pneumococcal bacteria. It will not prevent all pneumococcal disease.

PPSV23 is recommended for:

- All adults 65 years of age and older,
- Anyone 2 through 64 years of age with certain long-term health problems,
- Anyone 2 through 64 years of age with a weakened immune system,
- Adults 19 through 64 years of age who smoke cigarettes or have asthma.

Most people need only one dose of PPSV. A second dose is recommended for certain high-risk groups. People 65 and older should get a dose even if they have gotten one or more doses of the vaccine before they turned 65.

Your healthcare provider can give you more information about these recommendations.

Most healthy adults develop protection within 2 to 3 weeks of getting the shot.

3 Some people should not get this vaccine

- Anyone who has had a life-threatening allergic reaction to PPSV should not get another dose.
- Anyone who has a severe allergy to any component of PPSV should not receive it. Tell your provider if you have any severe allergies.
- Anyone who is moderately or severely ill when the shot is scheduled may be asked to wait until they recover before getting the vaccine. Someone with a mild illness can usually be vaccinated.
- Children less than 2 years of age should not receive this vaccine.
- There is no evidence that PPSV is harmful to either a pregnant woman or to her fetus. However, as a precaution, women who need the vaccine should be vaccinated before becoming pregnant, if possible.

CDC U.S. Department of Health and Human Services Centers for Disease Control and Prevention

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

About half of people who get PPSV have mild side effects, such as redness or pain where the shot is given, which go away within about two days.

Less than 1 out of 100 people develop a fever, muscle aches, or more severe local reactions.

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**

5 What if there is a serious reaction?

What should I look for?

Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement
PPSV Vaccine

4/24/2015

Office Use Only

VACCINE INFORMATION STATEMENT

Pneumococcal Conjugate Vaccine (PCV13)

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Vaccination can protect both children and adults from **pneumococcal disease**.

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact. It can cause ear infections, and it can also lead to more serious infections of the:

- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain and spinal cord (meningitis).

Pneumococcal pneumonia is most common among adults. Pneumococcal meningitis can cause deafness and brain damage, and it kills about 1 child in 10 who get it.

Anyone can get pneumococcal disease, but children under 2 years of age and adults 65 years and older, people with certain medical conditions, and cigarette smokers are at the highest risk.

Before there was a vaccine, the United States saw:

- more than 700 cases of meningitis,
- about 13,000 blood infections,
- about 5 million ear infections, and
- about 200 deaths

in children under 5 each year from pneumococcal disease. Since vaccine became available, severe pneumococcal disease in these children has fallen by 88%.

About 18,000 older adults die of pneumococcal disease each year in the United States.

Treatment of pneumococcal infections with penicillin and other drugs is not as effective as it used to be, because some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

2 PCV13 vaccine

Pneumococcal conjugate vaccine (called PCV13) protects against 13 types of pneumococcal bacteria.

PCV13 is routinely given to children at 2, 4, 6, and 12–15 months of age. It is also recommended for children and adults 2 to 64 years of age with certain health conditions, and for all adults 65 years of age and older. Your doctor can give you details.

3 Some people should not get this vaccine

Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine, to an earlier pneumococcal vaccine called PCV7, or to any vaccine containing diphtheria toxoid (for example, DTaP), should not get PCV13.

Anyone with a severe allergy to any component of PCV13 should not get the vaccine. *Tell your doctor if the person being vaccinated has any severe allergies.*

If the person scheduled for vaccination is not feeling well, your healthcare provider might decide to reschedule the shot on another day.

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Problems reported following PCV13 varied by age and dose in the series. The most common problems reported among children were:

- About half became drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a fever over 102.2°F.
- Up to about 8 out of 10 became fussy or irritable.

Adults have reported pain, redness, and swelling where the shot was given; also mild fever, fatigue, headache, chills, or muscle pain.

Young children who get PCV13 along with inactivated flu vaccine at the same time may be at increased risk for seizures caused by fever. Ask your doctor for more information.

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some older children and adults get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very small chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**

5 What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness—usually within a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.

  Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement

PCV13 Vaccine

11/05/2015

42 U.S.C. § 300aa-26

Office Use Only

APPENDIX H:

GUIDE FOR PROVIDERS

GUIDE FOR PROVIDERS

Pneumococcal vaccine timing for adults with certain medical conditions

Indicated to receive 1 dose of PPSV23 at 19 through 64 years

Includes adults with:

- chronic heart or lung disease
- diabetes mellitus
- alcoholism
- chronic liver disease

Also includes adults who smoke cigarettes

For those who have **not** received any pneumococcal vaccines, or those with unknown vaccination history:

- Administer 1 dose of PPSV23 at 19 through 64 years.
- Administer 1 dose of PCV13 at 65 years or older. This dose should be given **at least 1 year** after PPSV23.
- Administer 1 final dose of PPSV23 at 65 years or older. This dose should be given **at least 1 year** after PCV13 and at least 5 years after the most recent dose of PPSV23.

Indicated to receive 1 dose of PCV13 at ≥ 19 years and 1 or 2 doses of PPSV23 at 19 through 64 years

Includes adults with:

- cerebrospinal fluid (CSF) leaks*
- cochlear implants*
- sickle cell disease or other hemoglobinopathies
- congenital or acquired asplenia
- congenital or acquired immunodeficiencies
- HIV infection
- chronic renal failure
- nephrotic syndrome
- leukemia
- lymphoma
- Hodgkin disease
- generalized malignancy
- iatrogenic immunosuppression
- solid organ transplant
- multiple myeloma

For those who have **not** received any pneumococcal vaccines, or those with unknown vaccination history:

- Administer 1 dose of PCV13.
- Administer 1 dose of PPSV23 **at least 8 weeks** later.
- Administer a second dose of PPSV23 **at least 5 years** after the previous dose (**note: a second dose is not indicated for those with CSF leaks or cochlear implants*).
- Administer 1 final dose of PPSV23 at 65 years or older. This dose should be given **at least 5 years** after the most recent dose of PPSV23.

APPENDIX I:

VACCINE TIMING

Vaccine Timing

Pneumococcal Vaccine Timing for Adults

Make sure your patients are up to date with pneumococcal vaccination.

Two pneumococcal vaccines are recommended for adults:
- 13-valent pneumococcal conjugate vaccine (PCV13, Prevnar13®)
- 23-valent pneumococcal polysaccharide vaccine (PPSV23, Pneumovax®23)

PCV13 and PPSV23 should not be administered during the same office visit.

When both are indicated, PCV13 should be given before PPSV23 whenever possible.

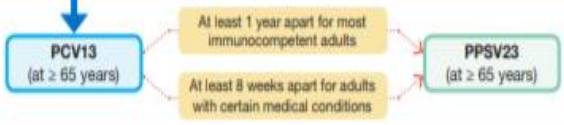
If either vaccine is inadvertently given earlier than the recommended window, do not repeat the dose.

One dose of PCV13 is recommended for adults:
- 65 years or older who have not previously received PCV13.
- 19 years or older with certain medical conditions and who have not previously received PCV13. *See Table 1 for specific guidance.*

One dose of PPSV23 is recommended for adults:
- 65 years or older, regardless of previous history of vaccination with pneumococcal vaccines.
  - Once a dose of PPSV23 is given at age 65 years or older, no additional doses of PPSV23 should be administered.
- 19 through 64 years with certain medical conditions.
  - A second dose may be indicated depending on the medical condition. *See Table 1 for specific guidance.*

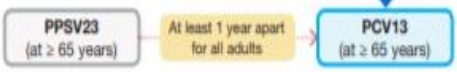
Pneumococcal vaccine timing for adults 65 years or older

For those who have not received any pneumococcal vaccines, or those with unknown vaccination history



- Administer 1 dose of PCV13.
- Administer 1 dose of PPSV23 **at least 1 year** later for most immunocompetent adults or **at least 8 weeks** later for adults with immunocompromising conditions, cerebrospinal fluid leaks, or cochlear implants. *See Table 1 for specific guidance.*

For those who have previously received 1 dose of PPSV23 at ≥ 65 years and no doses of PCV13



- Administer 1 dose of PCV13 **at least 1 year** after the dose of PPSV23 for all adults, regardless of medical conditions.

NCIRDig410 | 11.30.2015

www.cdc.gov/pneumococcal/vaccination.html

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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